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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,271	10/17/2001	Samuel Achilefu	MRD-72	6423

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EXAMINER

JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 10/22/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/981,271

Applicant(s)

ACHILEFU ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 3-7 and 10-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,8,9,15-17,20 and 21 is/are rejected.
- 7) ☒ Claim(s) 18, 19, and 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of Paper No. 9, filed 8/21/03, wherein claims 1, 22, 8, and 9 were amended.

Note: Claims 1-22 are pending.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

2. The Applicant's arguments filed 8/21/03 (Paper No. 9) to the rejection of claims 1, 2, 8, 9, 15-17, 20, and 21 made by the Examiner under 35 USC 102 and/or 103 have been fully considered and deemed non-persuasive for the reasons set forth below.

102 Rejection

The rejection of claims 1 and 2 under 35 USC 102(b) as being anticipated by Hasan et al (Journal of Controlled Release, 10 (1989), 107-117) is MAINTAINED for reasons of record in the office action mailed 5/21/03, Paper No. 8, and those set forth below.

Applicant asserts that the Hasan et al tetramethylindotricarbocyanine (TCC) is conjugated to two monoclonal antibodies while Applicant's structure has four bioactive molecules.

Applicant's arguments are not found persuasive because the claims do not *require* four bioactive molecules. Specifically, if Applicant is referring to the variables Y1, Y2, Z1, and Z2, the variable definitions include hydrogen, tumor specific agents, phototherapy agents, and various substitutents containing Bm and Dm. Hence, since

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the claim does not state that Y1, Y2, Z1, and Z2 cannot be hydrogen, for example, then the presence of four bioactive molecules are not required.

103 Rejection

The rejection of claims 1, 2, 8, 9, 15-17, 20, and 21 under 35 USC 103(a) as being unpatentable over Hasan et al (Journal of Controlled Release, 10 (1989), 107-117) is MAINTAINED for reasons of record in the office action mailed 5/21/03, Paper No. 8, and those set forth below.

Applicant asserts that there is no motivation to generate structurally similar structures to TCC wherein R10 and R11 are C2-C10 alkyl groups because the reference must be evaluated as a whole.

As stated in the previous office action, skilled practitioner would be motivated to generate compounds structurally similar to TCC wherein, for example, R10 and R11 are C2-C10 alkyl groups because (1) Hasan et al disclose the advantages of generating Mab-chromophore conjugates comprising TCC (for example, see page 116, 'Conclusion'). (2) Thus, a skilled practitioner in the art would recognize that homologous series have similar characteristics. Hence, the characteristics normally possessed by members of a homologous series are principally the same. As a result, the varying gradually from member to member by a CH₂ group, a chemists knowing the properties of one member of a series would in general know what to expect in adjacent members. In other words, since R10 and R11 of TCC is CH₃, a skilled practitioner

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would expect a compound wherein R10 and R11 are replaced with C2-C10 to have similar characteristics.

Applicant also asserts that Hasan et al does not suggest in vivo use. However, the reference discloses the advantages of the active Mab-chromophore conjugates and concludes that the characterization of the conjugates, the preparation of more effective conjugates, and suggests in vivo use in the conclusion of the document (see page 116, 'Conclusion'). Hence, a skilled practitioner in the art would be motivated to examine in vivo uses of the conjugates.

Withdrawn Claims

Claims 3-7 and 10-14 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

Note: It is duly noted that Applicant has requested that the withdrawn claims be considered. The withdrawn claims will not be considered because the search has not been expanded beyond the elected species and EXP#1 for reasons set forth above.

Claim Objections

Claims 18, 19, and 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Notes: Claims 18, 19, and 22 are allowable over the prior art of record for reasons of record in the office action mailed 8/21/03, Paper No. 8. However, it is duly

noted that Applicant asserts that claim 8 is allowable over the prior art and requests that the objection to claims 18, 19, and 22 that are dependent upon claim 8 be withdrawn. The claims are still objected to and Applicant is respectfully requested to review the rejection including claim 8 (see the 103 rejection above).

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308 - 2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



D. L. Jones
Primary Examiner
Art Unit 1616

October 21, 2003